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In re Application of	:
Ramani R. Runatunge et al	:
Serial No.: 10/608,333	: PETITION DECISION
Filed: June 30, 2003	:
Attorney Docket No.: 102258.153	:

This is in response to the petition under 37 CFR 1.144, filed May 18, 2005, requesting withdrawal of an improper restriction requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 and contained 58 claims, as filed. It is also noted that claim 1 was over 60 pages long. The examiner in a first Office action, mailed November 19, 2004, set forth a restriction requirement (not reproduced herein) dividing the claims into 25 groups. The requirement generally divides the claims into Groups I-XVI directed to compounds and compositions based on structural formulas I-XVI, as set forth in claim 1, Groups XVII-XXIV directed to methods of treatment of various diseases and conditions using the compounds/compositions of claim 1 and Group XXV directed to kits containing the compounds/compositions. The examiner also required an election of species if one of Groups I-XVI or XXV was elected or an election of a specific disease or condition if one of Groups XVII-XXIV were elected. The examiner stated that each of the compounds and compositions were different from those of the other groups based on classification and differing structure and that to search all groups would be burdensome on the Office. The methods were considered to be different based on the multitude of different diseases and conditions treated. The examiner further stated that upon election of a species the Office would review the claims and disclosure and determine the scope of the independent invention encompassing the elected compound/composition and limit examination thereto.

Applicants replied by electing Group II, directed to compounds and composition of Formula II, claims 1-2, 14-16, 28-39 and 55-57, in part and traversing the requirement. Applicants suggested a restriction requirement of 16 groups based on the 16 structural formulas in Claim 1 with all claims being common to each group. Applicants argued that the method of use claims should be examined with the compound/composition claims. Applicants also elected a species as required.

The examiner mailed a new Office action to applicants on February 18, 2005, acknowledging the election of Group II and the species identified. The examiner responded to the traversal noting that the various Groups of compounds were not related to each other and made the requirement Final. The examiner then defined the scope of the compounds to be examined based on the species elected limiting R^1, $R^{1'}$, R^2 and R^4 to single values and permitting only limited variation in R^5. The examiner then rejected claims 1-2, 14-16, 28-39 and 55-57 under 35 U.S.C. 112, first and second paragraphs, as failing to comply with the written description requirement noting that substituents R^1, $R^{1'}$, R^2, R^4 and R^5 are not defined in the specification or claims. The claims were also objected to as containing non-elected subject matter. Rejoinder of claims 40-50 was indicated as to be granted if limited to those diseases or conditions having support in the specification.

Applicants replied on May 18, 2005, by filing an amendment which canceled claim 1 replacing it with claim 59 limited to the compounds of Formula II (the elected Group) and modifying dependencies of other claims as needed. A petition with respect to the restriction requirement was filed concurrently

DISCUSSION

Applicants argue that restriction is not proper when the inventions are related and not patently distinct. Applicants argue that all claims are related as being directed to nitrosated or nitrosylated cyclooxygenase-2 inhibitor compounds. From applicants' initial argument it is presumed that the restriction requirement between the 16 formulas of original Claim 1 is not being argued, but rather the examiner's determination of the scope of the invention to be examined based on the species elected and the restriction between method and kit claims containing the compounds. Applicants argue that the examiner must show that the claims are separately classified, or have acquired a separate status in the art or have different fields of search.

Applicants reference US Patent 6,649,929 where compounds, compositions and kits of a single structure were examined and issued together. While such reference is indicative of what was done in a related application, each application is examined on its own merits and what is done in one application may not be appropriate in another application. However, general consistency of prosecution within the Office is desirable and generally found.

With respect to the examiner's determination of the scope of the invention to be examined based on the species elected, such is improper, as pointed out by applicants by referencing M.P.E.P. 803.02. The examiner having determined 16 separate groups of invention within original claim 1, each group consisting of a large number of related compounds sufficient to require an election of species within the group elected, could not then further restrict the compounds encompassed within the group by limiting the scope of invention to be examined as has been done here. M.P.E.P. 803.02 requires an examiner to determine whether the elected species first avoids the prior art. If so, the examiner is required to expand examination to a reasonable number of related species. If all of these are found to be patentable over the prior art then they are further examined to ensure they meet all other requirements for patentability. However, discovery of a species which is not patentable over the prior art mandates the entire claim to be rejected. The

examiner here has, to some extent, expanded the examination beyond the elected species, but has ~~found~~ identified no prior art which would render the limited scope of compounds examined unpatentable. Thus continued expansion of the scope of the species is required until a species is found that is not patentable over the prior art or a sufficient number (not necessarily all) of species have been found patentable over the prior art. If all other conditions for patentability are met then the compound/composition claims are considered allowable.

As the examiner has noted, upon determination of allowability of the compound/composition claims, method of use (i.e. treatment) claims (as well as kit claims) will be rejoined so long as they contain all of the limitations of the allowed compound/composition claims and will be examined for compliance with all other aspects of the statute to determine their patentability. Such rejoinder is at this time inappropriate as the examiner has not determined the patentability of the full scope of the compound/composition claims.

DECISION

The petition is **GRANTED** to the extent indicated above.

The application will be forwarded to the examiner for further consideration in view of the amendment filed concurrently with the petition..

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 703-308-3824 or by facsimile sent to the general Office facsimile number, 571-273-8300.

George C. Elliott
Director, Technology Center 1600